

6-2-03

# Office Action Summary

Application No.

10/031,403

Applicant(s)

MEHUL ET AL.

Examiner

Laurie Mayes

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 7, 8, 11, 14, 16-19, 21, 22, 24, 25 and 29 is/are allowed.
- 6) ☒ Claim(s) 6, 9, 12, 13, 15, 20, 23, 26-28 and 30-32 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-20 and 25 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the inventions share unity of invention.

Upon reconsideration, the examiner will examine claims 1-32 as one group of inventions.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 13, 15, 20 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 12, the language "effective amount" is indefinite as it is unclear what the effective amount is for. In claim 13, the language "intended to regulate the impairments of epidermal, normal or pathological proliferation or differentiation, comprising . . ." is indefinite because the term "epidermal" is an adjective. Is it intended to regulate impairments of the epidermal layer of skin or the epidermis? Also, "normal or pathological proliferation or differentiation" of what? In claim 30, the language " . . . to a synthetic peptide of said polypeptide" is unclear. The applicant may use the following language instead: " . . . or to said synthetic polypeptide as described in claim 1".

### ***Objections to Specification***

The use of the trademark COMPLETE (spec. p. 29) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

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Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Objections to Claims***

Claim 10 is objected to as containing an additional “in” (see “wherein in” in line 1) and as it contains a misspelling of the word “one” (line 2).

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention in claim 6 is directed to non-statutory subject matter. A “natural . . . polypeptide whose sequence in part comprises the sequence of the polypeptide as described in claim 1” is found naturally occurring in nature in the skin of animals.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Flavell et al. (US 5,747,294). Flavell et al. teach a recombinant protein that is obtained by expression of an expression vector pGex-2T that contains part of the sequence (for example, ATG) that codes SEQ ID NO: 2 (col. 27, lines 33-45 and Fig. 1a: Met/ ATG). Thus, all of the elements of claims 23 and 28 are anticipated by Flavell et al.

Claims 6, 9, 26-27 and 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Hillman et al. (US 6,046,315). Hillman et al. teach a recombinant DACP-1 which has an amino acid sequence with 99.6% identity to SEQ ID NO: 1 (see sequence listing cols. 35 and 36). Thus, Hillman et al. teach a recombinant protein that corresponds to part of SEQ ID NO: 1 (present claims 6 and 27). Hillman et al. also teach a recombinant expression vector that contains part of the nucleotide sequence that codes SEQ ID NO: 2 (present claim 26)(see the nucleotide sequence cols. 37 and 38 and claim 6). Further, the protein taught by Hillman et al. has an amino acid sequence with 99.6% identity to SEQ ID NO: 1 with an arginine at position 64 in place of a lysine. Hillman et al. teach that conservative substitutions such as a substitution of an arginine for a lysine are possible and would yield a functionally equivalent protein (col. 4, lines 17-38); absent evidence to the contrary, the mixture of DACP-1 polypeptides (col. 3, lines 60-66) could be obtained from the initial stages of proteolysis of SEQ ID NO: 1 wherein the amino acid at position 64 is the sole change (present claim 9). Hillman et al. also teach a method of preparing antibodies (present claims 30-31) comprising using the polypeptide DACP-1 (col. 19, lines 11-20). DACP-1 has an amino acid sequence with 99.6% identity to SEQ ID NO: 1 (present claim 32). Given the nearly identical amino acid sequences of DACP-1 and SEQ ID NO: 1, varying on only one amino acid, an antibody to DACP-1 would be expected to recognize

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SEQ ID NO: 1 also. Thus, all of the elements of claims 6, 9, 26-27 and 30-32 are taught by Hillman et al. and these claims are anticipated under 35 U.S.C. 102(e).


***Conclusion***

**Claims 6, 9, 12, 13, 15, 20, 23, 26-28 and 30-32 are rejected. No prior art has been found as to claims 1-8, 10-22, 24, 25 or 29.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

  
Laurie Mayes  
Patent Examiner  
Art Unit 1653  
May 19, 2003